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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/067,076	02/04/2002	Carol A. Wise	TEX871/4-006US/36000	4070

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EXAMINER

FREDMAN, JEFFREY NORMAN

ART UNIT	PAPER NUMBER
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1634

DATE MAILED: 01/13/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/067,076

Applicant(s)

WISE, CAROL A.

Examiner

Jeffrey Fredman

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 24 November 2003.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 38 and 41-53 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 38 and 43-53 is/are rejected.
- 7) ☒ Claim(s) 41 and 42 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 13) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.
a) ☐ The translation of the foreign language provisional application has been received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 5/10/02. 6) ☐ Other: _____

DETAILED ACTION

Election/Restrictions

1. Applicant's election without traverse of Group III, claims 38-53 in the paper filed November 24, 2003 is acknowledged.

Applicant's election of the SNP G688A is further acknowledged.

Priority

2. The current application claims priority to 09/710,693 and to 60/287,893. While the provisional application, 60/287,893 provides descriptive support for the claims, no support for the G688A polymorphism was found in application 09/710,693.

Consequently, priority is granted only until May 1, 2001, the filing date of the provisional application.

Claim Rejections - 35 USC § 112 – Written Description

3. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

4. Claims 38, 43-53 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

In analysis of the claims for compliance with the written description requirement of 35 U.S.C. 112, first paragraph, the written description guidelines note regarding genus/species situations that "Satisfactory disclosure of a ``representative number"

depends on whether one of skill in the art would recognize that the applicant was in possession of the necessary common attributes or features of the elements possessed by the members of the genus in view of the species disclosed." (See: Federal Register: December 21, 1999 (Volume 64, Number 244), revised guidelines for written description.)

Claims 38, 43-46 and 53 encompass a genus of nucleic acids which are different from those disclosed in the specification. Specifically, claim 38 permits conservative, but undisclosed, amino acid substitutions, which would necessarily result in undisclosed nucleic acid substitutions. The genus is immense, since SEQ ID NO: 20 is 1428 nucleotides in length, and possible changes in even a few amino acids would result in literally hundreds of trillions of different possible species. This large genus is represented in the specification by only the particularly named SEQ ID Nos. Thus, applicant has express possession of only two substitutions and the wildtype in the gene. Here, no common element or attributes of the sequences are disclosed, not even the presence of certain domains. No structural limitations or requirements which provide guidance on the identification of sequences which meet these functional limitations is provided. Further, these claims expressly encompasses allelic variations including insertions and deletions and is permissive of alternately spliced versions of the proteins, inactive precursor proteins which have a removable amino terminal end, while only specific amino acid sequences have been provided. No written description of alleles, of upstream or downstream regions containing additional sequence, or of alternative splice variants has been provided in the specification.

With regard to claims 47-52, these claims encompass the full length gene with conservative substitutions as above since the claims are of the open "comprising" format. So while the claim indicates a size for the oligonucleotide, the use of the term "comprising" negates this as an upper bound to the nucleic acid molecule.

Further, with regard to claim 53, no description of the hybridizing oligonucleotides is provided and this genus is also immense.

It is noted in the recently decided case The Regents of the University of California v. Eli Lilly and Co. 43 USPQ2d 1398 (Fed. Cir. 1997) decision by the CAFC that

"A definition by function, as we have previously indicated, does not suffice to define the genus because it is only an indication of what the gene does, rather than what it is. See *Fiers*, 984 F.2d at 1169- 71, 25 USPQ2d at 1605- 06 (discussing Amgen). It is only a definition of a useful result rather than a definition of what achieves that result. Many such genes may achieve that result. The description requirement of the patent statute requires a description of an invention, not an indication of a result that one might achieve if one made that invention. See *In re Wilder*, 736 F.2d 1516, 1521, 222 USPQ 369, 372- 73 (Fed. Cir. 1984) (affirming rejection because the specification does "little more than outlin[e] goals appellants hope the claimed invention achieves and the problems the invention will hopefully ameliorate."). Accordingly, naming a type of material generally known to exist, in the absence of knowledge as to what that material consists of, is not a description of that material. "

In the current situation, the definition of the "conservative substitutions" lacks any specific structure, and is precisely the situation of naming a type of material which is generally known to likely exist, but, except for the two specific substitutions, is in the absence of knowledge of the material composition and fails to provide descriptive support for the generic claim.

It is noted that in Fiers v. Sugano (25 USPQ2d, 1601), the Fed. Cir. concluded that

"...if inventor is unable to envision detailed chemical structure of DNA sequence coding for specific protein, as well as method of obtaining it, then conception is not achieved until reduction to practice has occurred, that is, until after gene has been isolated...conception of any chemical substance, requires definition of that substance other than by its functional utility."

The current situation is a definition of the compound without even the limitation of a functional utility, and without any definition of the particular conservative substitutions claimed.

In the instant application, certain specific SEQ ID NOs are described. Also, in Vas-Cath Inc. v. Mahurkar (19 USPQ2d 1111, CAFC 1991), it was concluded that:

"...applicant must also convey, with reasonable clarity to those skilled in art, that applicant, as of filing date sought, was in possession of invention, with invention being, for purposes of "written description" inquiry, whatever is presently claimed."

In the application at the time of filing, there is no record or description which would demonstrate conception of any nucleic acids other than those expressly disclosed which comprise substitutions or hybridizing oligonucleotides to SEQ ID NO: 20 or 22. Therefore, the claims fail to meet the written description requirement by encompassing sequences which are not described in the specification.

Claim Rejections - 35 USC § 102

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

6. Claims 38, 43-46 rejected under 35 U.S.C. 102(b) as being anticipated by Hillman et al (WO 00/06728).

Hillman teaches a nucleic acid molecule (as shown on the attached alignment) which is 99% identical to SEQ ID NO: 18 and encodes an amino acid sequence that comprises a conservative substitution of SEQ ID Nos: 20 and 22 (see attached alignment).

With regard to claim 43, Hillman teaches expression vectors (see page 75, claim 12).

With regard to claim 44, Hillman teaches plasmid expression vectors such as the Superscript system (see page 38, line 18).

With regard to claims 45 and 46, Hillman teaches placement of the expression vectors in host cells (see page 38, lines 30-35).

7. Claims 47-53 are rejected under 35 U.S.C. 102(e) as being anticipated by Fodor et al (U.S. Patent 6,582,908).

First, claim 47 must be interpreted with regard to the scope of the phrase "about 20 contiguous nucleotides". The phrase "about" permits some flexibility in the length of

the oligonucleotide. Since the specification lacks any definition of the term "about", it is deemed to be a broad term which permits the 10-mer nucleic acids of Fodor to apply.

Fodor teaches an array of every possible 10-mer oligonucleotide (see column 22, lines 14-16). This 10-mer array inherently comprises every possible 10-mer, including 10-mers which are 100% complementary to the G688A mutation and the G748C mutation. Further, with regard to claims 48-51, the 10-mer array inherently comprises every orientation, with the nucleotide at the 3' end or at the 5' end, since some 10-mers will have the mutation at the 3' end and some will have the mutation at the 5' end. With regard to claim 52, some of the 10-mers will inherently comprise the complement of the oligonucleotide of claim 47. Finally, with regard to claim 53, many of the 10-mers will hybridize to the nucleic acid molecule of claim 47 but will not hybridize to SEQ ID NO: 18 under appropriate hybridization conditions.

Double Patenting

8. Claims 38 and 43-46 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-9 of U.S. Patent No. 6,642,370. Although the conflicting claims are not identical, they are not patentably distinct from each other because Claims 1-9 of U.S. Patent No. 6,642,370 teach a nucleic acid molecule which encodes an amino acid sequence comprising conservative amino acid substitutions of SEQ ID Nos: 20 and 22. Further, claims 1-9 of U.S. Patent No. 6,642,370 teach the limitations of dependent claims 43-46, including expression control sequences, plasmids, host cells including those specifically recited.

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9. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Allowable Subject Matter

10. Claims 41 and 42 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

11. The following is a statement of reasons for the indication of allowable subject matter: The claims are indicated as allowable because claims 41 and 42 are limited to the specific sequences recited and the prior art does not teach these particular sequences.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jeffrey Fredman whose telephone number is (571)272-0742. The examiner can normally be reached on 6:30-4:00.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion can be reached on (571)272-0782. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

A handwritten signature in black ink, appearing to read 'Jeffrey Fredman', with a stylized flourish extending to the right.

Jeffrey Fredman
Primary Examiner
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